IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:		Confirmation No.:	3580
Nordine CHEIKH *et al.*		Art Unit:	1647
Appln. No.:	09/976,054	Examiner:	Marianne P. Allen
Filed:	October 15, 2001	Atty. Docket:	16517.256

Title: Nucleic Acid Molecules and Other Molecules Associated with Plants

APPELLANTS' REPLY BRIEF

Mail Stop Appeal Brief – Patent
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This is a reply to arguments raised in the Examiner's Answer mailed July 7, 2008 ("Examiner's Answer").

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Appellants do not believe any additional fees are due in conjunction with this filing. However, if any fees under 37 C.F.R. §§ 1.16 or 1.17 are required in the present application, including any fees for extensions of time, authorization to charge such fees is given in the accompanying transmittal letter.

1. Introduction

In the Final Office Action mailed November 13, 2007 ("Final Action"), the Examiner maintained the rejection of claims 20-23 and 25 under 35 U.S.C. § 112, first paragraph, as allegedly being drawn to new matter and as failing to comply with the enablement requirement.[1] On May 1, 2008, Appellants filed a Revised Appeal Brief ("Appeal Brief") to address the rejections of Claims 20-23 and 25.

In the Examiner's Answer, the Examiner provided additional arguments in response to points raised in the Appeal Brief in support of maintaining the rejections of claims 20-23 and 25 under U.S.C. § 112, first paragraph. Appellants wish to respond to the arguments raised in the Examiner's Answer with regard to the rejections of the claims. Further, Appellants submit that the outstanding rejections under 35 U.S.C. § 112, first paragraph, are improper.

2. 35 U.S.C. §112, Written Description

In the Examiner's Answer, the Examiner alleges that claims 20-23 and 25 fail to meet the written description requirement under U.S.C. § 112, first paragraph, because, allegedly, the claimed "transformed host cells and transformed plants containing the isolated polynucleotide alone (that is, not operably linked to other sequences needed for expression of the encoded polypeptide) are **not** contemplated." Examiner's Answer at page 9 (emphasis in original). Essentially, the Examiner's position is that the claims contain new matter because they do not explicitly recite the inclusion of regulatory

[1] Claims 12-17, 20-23 and 25 are pending in the application. Claims 12-17 have been allowed by the Examiner and are not addressed in this Reply Brief.

elements for expression of the claimed nucleic acid molecules in transformed host cells and plants. This position is wrong as a matter of law.

Further, the Examiner asserts that, with respect to claims 21 and 22, "[n]on-plant transgenic organisms are not contemplated [in the specification]." Examiner's Answer at page 9. Finally, with respect to claim 25, the Examiner asserts that transformed plants consisting of the transformed host cells of claim 21 are not disclosed or contemplated by the specification. *Id.* at 10. Both of these assertions are also incorrect.

A. The Application Clearly Contemplates Transformants Comprising the Claimed Nucleic Acid Molecules

At the outset, the specification undeniably discloses that Appellants contemplated the use of the claimed nucleic acid molecules in transformants as of the filing date of the application. For example, the first sentence under subheading (a) on page 82 of the specification, "Plant Constructs and Plant Transformants", states "[o]ne or more of the nucleic acid molecules of the present invention may be used in plant transformation or transfection." Specification at page 82, lines 17-19. Likewise, the specification also includes such statements with respect to fungal constructs and fungal transformants (*id.* at page 105, lines 4-8); mammalian constructs and transformed mammalian cells (*id.* at page 117, lines 17 through page 118, line 3); insect constructs and transformed insect cells (*id.* at page 123, lines 1-9); and bacterial constructs and transformed bacterial cells (*id.* at page 131, lines 5-13). These sentences alone clearly envision the inclusion of nucleic acid sequences without more in transformed plants and host cells.

B. The Claims Need Not Explicitly Recite Regulatory Elements

The crux of the Examiner's position in support of the rejection of pending claims 20-23 and 25 as allegedly containing new matter is that none of the claims "requires that the nucleic acid be in association with regulatory sequences such as promoters and transformed plants having nucleic acid sequences in the absence of such regulatory sequences are not disclosed." Examiner's Answer at page 6. This position is wrong for at least two reasons. First, it is not required that the claims recite such regulatory sequences because one of ordinary skill in the art could readily determine whether to include such regulatory sequences in order to express the claimed nucleic acid molecules in the claimed host cells. Second, the specification is replete with examples that provide additional guidance to one of ordinary skill in the art regarding the use of the claimed nucleic acid molecules in connection with regulatory sequences for multiple uses, including to achieve expression of the claimed nucleic acid molecules in transformed host cells and plants.

According to the Examiner, claims 20-23 and 25 contain new matter because the scope of these claims is broader than, for example, originally filed claims 6, 7 and 11. *See* Examiner's Answer pages 5-6. Indeed, the Examiner acknowledges that "[t]hese original claims clearly contemplate and disclose plants transformed with nucleic acid molecules operably linked to regulatory sequences and that express a protein." While this may be the case, the fact that the current claims do not recite these elements does not present an appropriate basis for a new matter rejection because, as stated above, the claims need not explicitly recite regulatory elements that may be used in connection with SEQ ID NO: 5 to express a protein in a transformed host cell or plant.

It is well established law that applicants are not required to include material in the specification, including the claims, that is well known or would be readily apparent to one of ordinary skill in the art upon reading the disclosure of the application. *See Paperless Accounting, Inc. v. Bay Area Rapid Transit System*, 804 F.2d 659, 664 (Fed. Cir. 1986) ("[a] patent applicant need not include in the specification that which is already known to and available to the public."); *Koito Mfg. Co., Ltd. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1156 (Fed. Cir. 2004) ("[t]his Court has repeatedly explained that a patent applicant does not need to include in the specification that which is already known to and available to one of ordinary skill in the art.") As Appellants have previously pointed out, the specification contains more than an ample description of the use of the claimed nucleic acid molecules with other regulatory elements to create transformed host cells and plants. *See, e.g.,* Appeal Brief at page 5; Appellants' Response under 37 C.F.R. §1.111 filed June 6, 2007; and the Specification at pages 82, line 17 to page 137, line 2. Given Appellants' disclosure, one of skill in the art would readily know which regulatory elements may be included in connection with SEQ ID NO: 5 to express, for example, a protein or partial protein encoded by SEQ ID NO: 5 in a transformed host cell.

The fact that the claims do not explicitly recite regulatory elements that are operably linked to SEQ ID NO: 5 does not mean that those elements may not be included in, for example, a transformed host cell or plant that would be contemplated by claims 20-23 and 25. As an analogy, one might claim a bicycle that comprises a new seat. Such a claim would not fail the written description requirement simply because the claim did not explicitly recite that the bicycle may also include at least one wheel, pedals, handle bars or other elements that a bike maker would know to include in a bicycle comprising

the new seat. In other words, one of ordinary skill in the biotechnical arts would not be precluded from including, where appropriate, regulatory elements that may be necessary to express SEQ ID NO: 5 in a host cell, regardless of whether those elements are explicitly required by the claims or not.

In fact, one of ordinary skill in the art would have the ability to select specific promoters, termination sequences and other regulatory elements that may be used in connection with SEQ ID NO: 5 depending on the specific intended use of SEQ ID NO: 5 in a particular transformed cell or organism. Returning to the bike analogy, a bike designer would know the specific type of wheels to include on the bike comprising the new seat depending on whether the bike was intended to be used for street riding or trail riding, for short trips versus long trips, by a child or an adult, etc. In much the same way, one of skill in the biotechnological arts would select different regulatory sequences to use in connection with SEQ ID NO: 5 depending on the type of host cell, the environment in which expression was to occur, and whether the goal is, for example, to express a protein or partial protein encoded by SEQ ID NO: 5 or to use SEQ ID NO: 5 to suppress the expression of another nucleic acid molecule. All of these regulatory sequences may be included in a transformed host cell or a transformed plant comprising SEQ ID NO: 5 contemplated by claims 20-23 and 25, and each embodiment would be apparent to one of ordinary skill in the art based upon Appellants' disclosure in the specification.

The Examiner's Answer incorrectly asserts that the "plant construct or plant transformant must be capable of producing the encoded protein." Examiner's Answer at page 6. In doing so, the Examiner incorrectly focuses her analysis on one portion of the specification that discusses the expression of the claimed nucleic acid molecules in a host

cell. *See id* at pages 6-9. Her conclusion is that "[t]he use of 'may' is not indicating that sequences needed for expression are optional or can be omitted, rather the use of 'may' is indicating the variety of choices for those sequences." *Id.* at page 9. This analysis is way off point.

In the first place, the Examiner's focus on the specification's discussion of the expression and overexpression of the claimed nucleic acid molecules in plants and plant cells misses the fact that the specification also discloses the use of the claimed nucleic acid molecules in transformed host cells and plants in connection with selectable and screenable markers (*see, e.g.,* Specification at page 89, line 4 though page 91, line 2) and for cosuppression (*see, e.g.,* Specification at page 101, line 12 through page 103, line 22). Neither of these uses necessarily *requires* the expression of a protein or partial protein encoded by SEQ ID NO: 5. Further, even assuming, *arguendo,* that the Examiner's position has any merit, it still would not negate the fact that the claims do not contain new matter because, as stated above, one of skill in the art would be able to easily ascertain which regulatory or other elements, if any, would be required to be used with the claimed nucleic acid molecules in a transformed host cells or transformed plant in order to achieve a particular desired result.

C. Transgenic Organisms and Transformed Plants Are Described in the Specification as Filed

The Examiner's Answer also alleges that Claims 21 and 22 are not supported by the specification because they encompass non-plant transgenic organisms. *See* Examiner's Answer at page 9. Further, the Examiner argues that Claim 25 is not supported by the specification because it is directed to a transformed plant consisting of

the host cells of claim 21, which are not limited to plant cells. *Id.* at pages 9-10. This position is simply wrong.

Throughout prosecution, the Examiner has ignored Appellants' repeated assertions that claims 21, 22 and 25 are adequately supported by the specification. For example, when requested by the Examiner to point out by page and line number where the limitations of these claims may be found, Appellants cited to portions of the specification that describe the claimed nucleic acid molecules in fungal host cells (Specification at page 105, line 4 through page 117, line 16); in mammalian host cells (Specification at page 117, line 17 through page 122, line 23); in insect host cells (Specification at page 123, line 1 through page 131, line 4); and in bacterial host cells (Specification at page 131, line 5 through page 137, line 2). *See* Office Action dated March 6, 2007 at page 4; and Response under 37 C.F.R. § 1.111 dated June 6, 2007 at page 5.

Further, as discussed in Section 2.A above, the specification clearly envisions and provides ample support for the inclusion of nucleic acid sequences without more in non-plant embodiments of the claimed transformed host cells. For example, the specification includes statements that the claimed nucleic acid molecules may be used in fungal constructs and fungal transformants (specification at page 105, lines 4-8); mammalian constructs and transformed mammalian cells (*id.* at page 117, lines 17 through page 118, line 3); insect constructs and transformed insect cells (*id.* at page 123, lines 1-9); and bacterial constructs and transformed bacterial cells (*id.* at page 131, lines 5-13). Nothing more is necessary to overcome the rejection under 35 U.C.S. § 112, first paragraph.

The Examiner simply ignored this support provided by Appellants and continued to make the unfounded assertion that "[n]on-plant transgenic organisms are not contemplated." Examiner's Answer at page 9. To the contrary, given Appellants' disclosure, and the knowledge available to one of ordinary skill in the biotechnological arts, it would be obvious that transgenic organisms comprising the transformed host cells of claims 21 and 22, including the transformed plants of claim 25, are fully disclosed in and supported by the specification.

In conclusion, the Examiner's position that claims 20-23 and 25 fail to meet the written description requirement of 35 U.S.C. § 112, first paragraph, because they allegedly contain new matter that was not presented in Appellants' application as filed is unsupportable. Therefore, Appellants request that the Board reverse this rejection.

3. The Claimed Invention is Enabled

The allegations in the Examiner's Answer that claims 20-23 and 25 fail to meet the enablement requirement of 35 U.S.C. § 112, first paragraph, are similarly misplaced. The Examiner focuses her analysis in support of this rejection on the assertion that SEQ ID NO: 5 "does not encode the complete sequence for the maize adenine phosphoribosyl transferase." Examiner's Answer at page 14. Moreover, the Examiner states that "the basis of the rejection is **how to use** the claimed transformed host cells and transformed plants." *Id.* at page 17 (emphasis in original). This assertion misses the point.

The Examiner argues that "Appellant's arguments [in the Appeal Brief] do not address **how to use** the claimed transformed host cells and transformed plants **in the absence of any expression.**" Examiner's Answer at page 17 (emphasis in original). First, this argument does not recognize that the claims do not require expression of the claimed nucleic acid molecules in the claimed transformed host cells and plants. Second,

as with the arguments presented by the Examiner in support of the new matter rejection, this argument misses the point that other uses for the claimed transformed host cells and plants are disclosed throughout the specification. *See, e.g.,* Specification at page 89, line 4 though page 91, line 2 (use of SEQ ID NO: 5 in the claimed host cells in connection with selectable and screenable markers); and at page 101, line 12 through page 103, line 22 (use of SEQ ID NO: 5 in the claimed host cells for cosuppression. As stated above, neither of these uses necessarily *requires* the expression of a protein or partial protein encoded by SEQ ID NO: 5.

Finally, the expression of the SEQ ID NO: 5 is not required in order to use the claimed host cells and transformed plants. In particular, the Examiner has already acknowledged that SEQ ID NO: 5 has utility in that it is useful as a probe for isolating a nucleic acid molecule that encodes a full length maize adenine phosphoribosyl transferase. *See* Office Action mailed September 27, 2006 at page 7. Thus, at the very least, the claimed transformed host cells and plants may be used to replicate SEQ ID NO: 5. Such a use does not require that the claimed transformed host cells and plants encode a full length maize adenine phosphoribosyl transferase.

In view of the above arguments, Appellants assert that the rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement is incorrect and respectfully request that the Board reverse this rejection.

CONCLUSION

In view of the foregoing, Applicants respectfully request that the Board of Patent Appeals and Interferences reverse the pending rejections and that the subject application be allowed forthwith.

Respectfully submitted,

Date: September 3, 2008

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CLAIMS APPENDIX

Claim 12 (Allowed). A substantially purified nucleic acid molecule comprising a nucleic acid sequence having the full-length sequence of SEQ ID NO: 5 or complement thereof.

Claim 13 (Allowed). The substantially purified nucleic acid molecule according to claim 12, wherein said nucleic acid molecule consists of a nucleic acid sequence having the full-length sequence of SEQ ID NO: 5 or complement thereof.

Claim 14. (Allowed) A substantially purified nucleic acid molecule having between 90% and 100% sequence identity with a nucleic acid molecule having the full-length sequence of SEQ ID NO: 5 or complement thereof.

Claim 15. (Allowed) The substantially purified nucleic acid molecule of claim 14, wherein said substantially purified nucleic acid molecule has between 95% and 100% sequence identity with SEQ ID NO: 5 or complement thereof.

Claim 16. (Allowed) The substantially purified nucleic acid molecule of claim 15, wherein said substantially purified nucleic acid molecule has between 98% and 100% sequence identity with SEQ ID NO: 5 or complement thereof.

Claim 17. (Allowed) The substantially purified nucleic acid molecule of claim 16, wherein said substantially purified nucleic acid molecule has between 99% and 100% sequence identity with SEQ ID NO: 5 or complement thereof.

Claim 20. A transformed plant comprising a recombinant nucleic acid molecule having the nucleic acid sequence of claim 12.

Claim 21. A transformed host cell comprising a recombinant nucleic acid molecule having the nucleic acid molecule of claim 12.

Claim 22. The host cell of claim 21, wherein said host cell is a plant cell.

Claim 23. A transformed plant comprising the host cell of claim 21.

Claim 25. A transformed plant consisting of host cells of claim 21.